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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/057,748

Applicant(s)

KORFHAGE ET AL.

Examiner

David Lamberson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 2 of this application. Claim 2 cites as a limitation a range of about 1-64 mM for the final concentration of ammonium sulfate in a composition. Neither provisional application 60/264,508 nor 60/264,488 recites this limitation in the specification or claims.

### *Specification*

The disclosure is objected to because of the following informalities: the term "destroying" is misused several times as an adjective (see p. 5, line 14; p. 11, line 20, etc.). Applicant appears to want to use the term "destructive" instead. Additionally, it is not clear what the meaning of (PDAR GAPDH) is on page 14.

Appropriate correction is required.

The use of the trademark SYBERGREEN™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Concerning the Figures and the Brief Description of the Drawings section, there are several errors:

In Figure 3, the data seems contradictory to the inventor's conclusion. It appears that the RT-PCR reaction is more effective in the presence of the cationic detergent, than it is in the absence of the detergent.

In the brief description of Figures 4-6, the applicant claims that multiple samples were tested, yet there are no error bars in the figures.

In the brief description of Figures 5 and 6, there is no indication of what (A) represents.

In the brief description of Figure 7, there is no indication of what the different lanes represent.

In the brief description of Figure 14, there is no indication of what the different bars represent.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 (and their dependent claims) do not recite a step which refers back to the preambles of the claims. The preambles recite a method for RNA purification, but no step refers

to actually purifying the RNA. It is unclear if there are additional steps that must be performed in the method to purify the RNA. Additionally, it is unclear in claims 5-14 if the indicated contaminants remain in the composition following RNA purification because the purification step is not indicated.

Claim 11 contains the trademark/trade name SYBRGREEN™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an instrument designed to measure gas release and, accordingly, the identification/description is indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 3-8, 10 and 12-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Lader (International Publication Number WO 00/06780).

The instant application claims a method of RNA purification comprising adding ammonium sulfate to a composition comprising RNA, where the final concentration of ammonium sulfate in the composition is below 20g/100ml. As per standard chemical nomenclature, g/ml is a representative of percent in solution, thus 20g/100ml is equivalent to 20%. Concerning claim 1, Lader refers to a method for RNA preservation (page 5, lines 19-20) using a range of ammonium sulfate concentrations (page 6, lines 9, 18-21) where a preferred method also results in the isolation of the RNA (page 10, lines 9-10). Lader further recites a method where the samples contain 0, 10, 20, 30, 40, 50, or 70 % ammonium sulfate (see Example 5, pages 22-23), and had previously stated that the concentration may be a range defined between any two salt concentrations (page 6, lines 18-21). Concerning claim 3, the range of 5-32 mM also falls within the percentage range as indicated by Lader, as will be obvious to anyone who is familiar with the concept of molarity (conversion of molarity to percentage dictates a range of 0.065%-0.96%). Concerning claim 4, 10 mM (or 0.13%) is also within the range as indicated by Lader as indicated above. Furthermore, RNA binding agents, polyamines (such as spermidine, spermine, etc.), a cationic detergent, actinomycin, charged polysaccharides, glycoproteins and nucleophiles are all present in cell lysates (or buffers in

which the cells are lysed). As a result, when claims 5-8, 10 and 12-14 are dependent on claim 1, they would also be anticipated by Lader because the compositions from which RNA is isolated in that method would inherently contain those compounds as contaminants.

Claims 2, 5-8, 10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lader (International Publication Number WO 00/06780).

The instant application claims a method of RNA purification comprising adding ammonium sulfate to a composition comprising RNA, where the final concentration of ammonium sulfate in the composition is about 1-64 mM. As per standard chemical nomenclature, g/ml is a representative of percent in solution, thus 20g/100ml is equivalent to 20%. Concerning claim 2, it will be obvious to those familiar with chemistry and the concept of molarity that the mM range recited in claim (1-64 mM) corresponds to a percentage range of 0.013%-1.92% ammonium sulfate, which falls within the range of 0-10%, as indicated by Lader (see above analysis). Furthermore, RNA binding agents, polyamines (such as spermidine, spermine, etc.), a cationic detergent, actinomycin, charged polysaccharides, glycoproteins and nucleophiles are all present in cell lysates (or buffers in which the cells are lysed). As a result, when claims 5-8, 10 and 12-14 are dependent upon claim 2, they would also be anticipated by Lader because the compositions from which RNA is isolated in that method would inherently contain those compounds as contaminants.

Claims 1-8, 10 and 12-14 are rejected under 35 U.S.C. 102(e) as being patented by Lader (US Patent No. 6,204,375).

The instant application claims a method of RNA purification comprising adding ammonium sulfate to a composition comprising RNA, where the final concentration of ammonium sulfate in the composition is below 20g/100ml. As per standard chemical nomenclature, g/ml is a representative of percent in solution, thus 20g/100ml is equivalent to 20%. Concerning claim 1, Lader refers to a method for RNA preservation (see column 3, lines 24-25) using a range of ammonium sulfate concentrations (see column 3, lines 57-65) where a preferred method also results in the isolation of the RNA (see column 5, lines 57-59). Lader further recites a method where the samples contain 0, 10, 20, 30, 40, 50, or 70 % ammonium sulfate (see column 7, lines 25-26), and had previously stated that the concentration may be a range defined between any two salt concentrations (see column 3, lines 57-65). Concerning claim 2, it will be obvious to those familiar with chemistry and the concept of molarity that the mM range recited in claim (1-64 mM) corresponds to a percentage range of 0.013%-1.92% ammonium sulfate, which falls within the range of 0-10%, as indicated by Lader (see above analysis). Concerning claim 3, the range of 5-32 mM (or 0.065%-0.96%) also falls within the percentage range as indicated by Lader. Concerning claim 4, 10 mM (or 0.13%) is also within the range as indicated by Lader. Furthermore, RNA binding agents, polyamines (such as spermidine, spermine, etc.), a cationic detergent, actinomycin, charged polysaccharides, glycoproteins and nucleophiles are all present in cell lysates (or buffers in which the cells are lysed). As a result, when claims 5-8, 10 and 12-14 are dependent on claim 1, they would also be anticipated by Lader because the compositions from which RNA is isolated in that method would inherently contain those compounds as contaminants.



***Allowable Subject Matter***

There are no allowable claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding, or relating to attachments to the Office Action, should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David A. Lambertson  
August 9, 2002

DAVID GUZO  
PRIMARY EXAMINER  
